Glaws

PENG LIM ENTERPRISE CO., LTD.
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TAIWAN, R.O.C
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K062947

5. 510(K) SUMMARY

DEC 14 2006

PENG LIM High Speed Air Turbine Handpiece
Models: Super-AIR and Super-QD series

510K:

Submitted by: **PENG LIM ENTERPRISE CO., LTD.**
67 HWA RONG RD., 2F, KU SHAN DIST., KAOHSIUNG, TAIWAN, ROC

Contact person: Dr. Jen, Ke-Min
No.58, Fu-Chiun Street, Hsin-Chu City,Taiwan, ROC
Tel: 886-3-5208829 fax: 886-3-5209783
E-mail: ceirs.jen@msa.hinet.net

Date Summary Prepared: September 24, 2006

Name of the Device: Dental Air-Powered Handpiece

Classification: Dental Air-Powered Handpiece (class I medical device; 21 CFR 872.4200)
Product code: EFB
Panel: 72

- Predicate Device: Dental Air-Powered Handpiece,
models: TIGER 100, TIGER 101, TIGER 200, TIGER 201, TIGER 202
510K No –K052822

- Statement of Intended Use: The PENG LIM High Speed Air Turbine Handpieces are intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations and restorations and polishing teeth.

  ⚠ CAUTION: Federal (US) law restricts the use of this device to licensed professionals.

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- Performance Data: The claim of substantial equivalence is based on comparisons of formulations and intended uses of the PENG LIM High Speed Air Turbine Handpiece, models: Super-AIR and Super-QD series and its claimed predicate.

- Conclusion: Based on the information in the notification, PENG LIM Enterprise Co., Ltd. believes that High Speed Air Turbine Handpieces, models: Super-AIR and Super-QD series are substantially equivalent to the claimed predicate, i.e., *Dental Air-Powered Handpiece, models: TIGER 100, TIGER 101, TIGER 200, TIGER 201, TIGER 202,* (K052822).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Jen Ke Min
Peng Lim Enterprise Company, Limited
No. 58, Fu-Chiun Street
Hsin-Chu City, 30067
Taiwan R.O.C

DEC 1 4 2006

Re: K062947
Trade/Device Name: PENG LIM High Speed Air Turbine Handpiece, Models: Super-AIR and Super-QD Series
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: September 23, 2006
Received: October 17, 2006

Dear Dr. Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

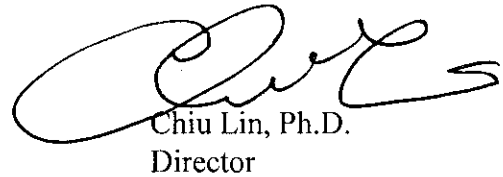
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062947

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Indications for Use

510 (K) Number (If Known): K

- **Device Name:** *PENG LIM High Speed Air Turbine Handpiece,*
  Models: Super-AIR and Super-QD series

Indications for Use :

- *PENG LIM High Speed Air Turbine Handpiece, models: Super-AIR and Super-QD series are intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations and restorations and polishing teeth.*
- *PENG LIM High Speed Air Turbine Handpiece carries the following label:*

⚠ *CAUTION: Federal (US) law restricts the use of this device to licensed professionals.*

Prescription Use √ AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Sara Runner Concurrence of CDRH, Office of Device Evaluation (ODE)

( )
[illegible] Anesthesiology, General Hospital,
[illegible]ion Control, Dental Devices
(510(k) Number) K062947